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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,257	02/08/2002	Boyong Li	141-242A	9034

47888 7590 05/27/2008
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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
05/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/071,257	LI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 2/19/08

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-6 and 8-22 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Percel et al (US 2001/0046964 hereafter '964). The claims are drawn to an enteric-coated dosage form comprising a core, a coating and an immediate release component. The core comprises a carrier and bupropion.

3. The '964 patent teaches an extruded [0007] controlled release tablet dosage form comprising an enteric coating on a core [0010] comprising bupropion (claim 6). The core comprises a binder such as hydroxypropylmethylcellulose [0006]. The formulation comprises

immediate release beads that are not coated with enteric polymers (abstract, 0004). The enteric polymers include those well known in the art such as cellulose acetate phthalate, polyvinyl acetate phthalate [0010]. The polymers maybe water insoluble such as ethylcellulose or methacrylic acid derivatives [0011]. The enteric polymers include Eudragit polymers such as L100, which is insoluble below a pH of 5.5 [0010].

4. Regarding the once-daily administration of the dosage from, it is the position of the Examiner that the limitations do not impart patentability since it does not further define a structural limitation and is merely a future intended use. The '964 patent teaches the same structural formulation as the instant claims for the same purpose. By meeting each of the claimed structural limitations, the formulation of the '964 patent would inherently meet any functional limitations or be capable of any future intended uses as well.

5. Regarding the in vivo plasma profile it is the position of the Examiner that such limitations would be inherent to any formulation meeting the structural limitations of the instant invention. Since plasma profiles are determined by the physical characteristics of a dosage form such as the polymer types, concentration and configuration, along with the types and concentration of the particular drugs, it is the position of the Examiner that any dosage from meeting the physical limitations of the instant invention would also meet any in vivo plasma profiles claimed. The '964 patent teaches an extruded composition comprising a core which further comprises a carrier and at least one aminoketone antidepressant. The '964 patent further teaches the inclusion of each polymer claimed. Therefore it is the position of the Examiner that since each physical characteristic of the instantly claimed dosage from is met by the teachings of

the '964 patent, the in vivo plasma profile is also met inherently. For these reasons at least the disclosures render the claims anticipated.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-6 and 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Percel et al (US 2001/0046964 hereafter '964).

3. As discussed above the '964 patent discloses an extruded controlled release dosage from comprising a core, which comprises a carrier and an aminoketone antidepressant. The '964 patent is however silent to the specific plasma profile. As discussed above this limitation would be an inherent feature of the instant invention. Further the plasma profile would have been obvious to one of ordinary skill in the art. Since the general conditions of the claims have been met by the '964 patent, specifically the same polymers and drugs are used in an identical formulation, any manipulation of these parameters would be obvious to one of ordinary skill in the art. Likewise results falling from this manipulation would be obvious to one of ordinary skill

in the art. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

4. Further The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

5. With these things in mind it would have been obvious to one of ordinary skill in the art to optimize the parameters of the '964 patent in order to achieve the desired plasma release rate since the patent discloses the same structural elements. It would have been obvious to optimize the component concentrations with an expected result of a controlled release formulation with improved release.

Response to Arguments

Applicant's arguments filed 2/19/08 have been fully considered but they are not persuasive. Applicant argues that;

The '964 patent does not anticipate nor obviate the instant claims since the patent does not discloses a once-a-day formulation, or the in vivo release properties of the instant claims.

Regarding this argument, it remains the position of the Examiner that the '964 patent continues to anticipate and obviate the claims. Applicant argues that '964 patent cannot disclose a once-a-day formulation since it only has release data for 12 hours. Applicant argues that once-a-day formulation must release active agent for 12-24 hours while the '964 only has data for up to 12 hours, and thus is not a once-a-day formulation. However applicant is ignoring the available data in the '964 patent that discloses that though data is available for up to 12 hours, the formulation is not completely released after 12 hours. The formulation of the '964 patent continues to release active agent beyond the 12 hour mark making it at least a once-a-day formulation by Applicant's own definition. Regardless of these disclosures however, the specific release profiles of the '964 patent are irrelevant. The release profiles of the instant claims are based off of in vivo testing of a particular formulation. This particular formulation comprises a core comprising a carrier and a concentration of bupropion, an immediate release component, a binder and an enteric coating. The in vivo release profile is an inherent feature of the composition and cannot be separated from it. In mass production, all formulation comprises these same elements would be expected to perform in a similar way. Their release rates would be inherent properties whether tested or not since the release profile cannot be separated from the composition and the compositions are all essentially identical. It is the position of the Examiner that composition of the '964 patent is sufficiently identical tot hat of the instant claims and would inherently have the same in vivo release rates regardless of whether the prior art discloses them

or not. The instant claims recite a core, drug, immediate release components, a binder and coating. The '964 patent discloses the same core structure, drug, identical binders and enteric coating polymers. The dosage form is a solid tablet (extruded) as recited in the instant claims. For all intents and purposes the formulations are identical, and as such would have the same release profile when tested. Regarding the choosing of bupropion as the active agent, the '964 patent discloses various active agents included in the formulation. Applicant argues that since the list is so exhaustive, there would be no way of choosing bupropion from the list. However claim 6 presents a finite list of active compounds all suitable for release with the structure of the formulation. Each compound is well known and has been well studied. There would be no unexpectedness in substituting one compound for the other from the finite list. The finite list of active agents provides a clear teaching and suggestion for the controlled extended release of bupropion in an extruded tablet dosage form. For these reasons the claims remain anticipated and obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618